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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,952	04/16/2004	Inder Raj S. Makin	END5311USNP	8216
27805	7590	08/08/2007		
THOMPSON HINE L.L.P. Intellectual Property Group P.O. BOX 8801 DAYTON, OH 45401-8801			EXAMINER FERNANDEZ, KATHERINE L	
			ART UNIT 3768	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/825,952

Applicant(s)

MAKIN ET AL.

Examiner

Katherine L. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date  
:7/9/2004,10/27/2006,9/11/2006, 1/4/2007,2/21/2007,4/16/2004. **8/2/2007**

***Information Disclosure Statement***

1. The Information Disclosure Statements are acknowledged. The Information Disclosure Statements meet the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein have been considered.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-2, 4, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Diederich (US Patent No. 5,620,479).

Diederich discloses an ultrasound medical system comprising an ultrasound transducer assembly (10) having a longitudinal axis, having a distal end, (column 6, lines 43-62) and having: a) a first ultrasound transducer disposed proximate the distal end and having a substantially-fully cylindrical ultrasound-emitting surface which is substantially coaxially aligned with, and outwardly-facing from, the longitudinal axis; b) a second ultrasound transducer having a substantially-fully-cylindrical ultrasound-emitting surface which is substantially coaxially aligned with, and outwardly-facing from, the longitudinal axis; and c) a

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third ultrasound transducer disposed longitudinally between first and second ultrasound transducers and having an ultrasound-emitting surface which includes at least a concave surface portion (i.e. cylindrical in shape) (column 6, line 58 – column 7, line 22, referring to plurality of tubular piezoceramic transducers which are substantially cylindrical in shape); also see Figure 1, three transducers (16) are arranged in above described manner). As can be seen from Figure 1, the transducers (16) are arranged such as a first ultrasound transducer is disposed at the distal end, and a third transducer is disposed proximate to the first and second ultrasound transducers (See Figure 1). See Figures 1-3. With regards to claim 6, the first and second ultrasound transducers are ultrasound-medical-treatment-only ultrasound transducers (column 3, lines 7-18, referring to ultrasound applicator being used for thermal therapy; column 10, lines 37-48, referring to transducers behaving as “hot” sources). The ultrasound transducers have only one ultrasound transducer element (16) (column 7, lines 31-34, the transducers are referred to as single transducer elements; also see Figure 1).

4. Claims 31-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Manna et al. (US 6,902,536).

Manna et al. disclose an ultrasound medical system comprising a transducer assembly having a longitudinal axis, having a distal end, (column 3, lines 29-57) and having: a) a first RF (radio-frequency) medical-treatment electrode (32); and b) an ultrasound medical transducer (62) disposed longitudinally proximal or distal to the first RF medical treatment electrode (column 7, line 58 through column 8, line 37; see Figures 3-5). Further, as can

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be seen in Figure 5A, the first RF medical-treatment electrode (32) is disposed proximate the distal end, and wherein the ultrasound medical transducer (62) is disposed proximate, and longitudinally proximal to, the first RF medical-treatment electrode. Manna et al. disclose that their system can also include a second RF medical-treatment electrode (34), wherein the ultrasound medical transducer(40) is disposed longitudinally between the first and second RF medical treatment electrodes (column 7, lines 4-36 and lines 28-42). See Figure 3B. The first RF medical-treatment electrode is disposed at the distal end and tapers to a tissue-penetrating edge (44) (column 8, lines 4-6, referring to surgeon sliding sheath to forward to place the electrodes in contact with the tissue; also see Figure 5A and 5B).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3, 9, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich in view of Unger et al. (US Patent No. 5,558,092).

As discussed above, Diederich meets the limitations of claim 1. However, they do not specifically disclose that at least one of the first, second and third ultrasound transducers (or all of the transducers) have a plurality of ultrasound transducer elements, nor do they disclose that the transducers surface is

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substantially-entirely planar. Unger et al. disclose a method and apparatus for performing diagnostic ultrasound simultaneously with the application of therapeutic ultrasonic waves to a region of a patient (column 1, lines 9-13). They disclose that their system includes an ultrasonic transducer assembly that comprises a linear array (16) of therapeutic transducer elements and also comprises of a first and second linear arrays of diagnostic transducer elements (12,14) (column 7, line 47 through column 8, line 13). As can be seen from Figure 1, each transducer array (i.e. therapeutic and diagnostic) has a plurality of ultrasound transducer elements (12,14,16). Further, the transducer elements are arranged on a common platform having a substantially planar upper surface (column 7, lines 19-31). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the ultrasound transducers in the invention of Diederich have a plurality of ultrasound transducer elements. The motivation for doing so would have been to enlarge the field of view, increase the imaging sensitivity, and increase the resolution, as taught by Unger et al. (column 7, lines 24-31).

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich in view of Vitek et al. (US Patent No. 6,613,004).

As discussed above, Diederich meets the limitations of claim 1. However, they do not specifically disclose that the ultrasound-emitting surface of the third ultrasound transducer in its entirety has a substantially-spherically-focused shape. Vitek et al. disclose a system and method for performing noninvasive surgical procedures using focused ultrasound, and more particularly to systems

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and method for creating longer necrosed volumes using a focused ultrasound transducer array (column 1, lines 8-12). They disclose that their invention includes the use of a transducer with a substantially concave or bowl shape, preferably a "spherical cap" shape (column 3, line 65 through column 4, line 5). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the transducer have a substantially-spherically-focused shape. The motivation for doing so would have been to increase the targeted volume per sonication, as taught by Vitek et al. (column 1, lines 62-66).

8. Claims 7, 10-11, 13, 16-17, 19, 22-23, 25, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich in view of Makin et al. (US 2003/0018266).

With regards to claims 7, 10-11, and 13, as discussed above, Diederich meets the limitations of claims 1-2, 4, 6, and 8. However, Diederich does not specifically disclose that the third transducer is an ultrasound-medical-treatment-and-imaging ultrasound transducer. Makin et al. disclose an ultrasound medical system including an ultrasound transducer assembly which is insertable into a patient, which has a longitudinal axis, and which has a plurality of ultrasound transducers. They disclose that at least one of the transducers is an ultrasound imaging and medical-treatment transducer (pg. 6, paragraph [0065]; pg. 7, paragraph [0076]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the third transducer in the system of Diederich be an ultrasound-medical-treatment-and-imaging ultrasound



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transducer. The motivation for doing so would have been to monitor the ultrasound treatment, as taught by Makin et al. (pg. 1, paragraph [0004]).

With regards to claim 16-17 and 19, Diederich meets most of the limitations as discussed above. However, Diederich does not specifically disclose that the third ultrasound transducer is an ultrasound-medical-imaging-only ultrasound transducer. Makin et al. disclose that at least one of the transducers is an ultrasound imaging transducer (pg. 6, paragraph [0065]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the third transducer in the system of Diederich be an ultrasound-medical-imaging-only ultrasound transducer. The motivation for doing so would have been to monitor the ultrasound treatment, as taught by Makin et al. (pg. 1, paragraph [0004]).

With regards to claims 22-23 and 25, Diederich meets most of the limitations as discussed above. However, they do not specifically disclose that that the first and second ultrasound transducers are ultrasound medical-treatment-and-imaging ultrasound transducers. Makin et al. disclose that at least one of the transducers is an ultrasound imaging and medical-treatment transducer (pg. 6, paragraph [0065]; pg. 7, paragraph [0076]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the first and second transducers in the system of Diederich be ultrasound-medical-treatment-and-imaging ultrasound transducers. The motivation for doing so would have been to monitor the ultrasound treatment, as taught by Makin et al. (pg. 1, paragraph [0004]).

With regards to claim 30, as discussed below for claim 29, Diederich meets most of the limitations of claim 30. However, although Diederich discloses that the transducers can be used for therapy, they do not specifically disclose that one and the other transducers are different types of medical-treatment-only type, medical treatment-and-imaging type, and medical-imaging-only type transducers. Makin et al. disclose that at least one of the transducers is an ultrasound imaging and medical-treatment transducer (pg. 6, paragraph [0065]; pg. 7, paragraph [0076]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have either the first and second transducers in the system of Diederich be an ultrasound-medical-treatment-and-imaging ultrasound transducer. The motivation for doing so would have been to monitor the ultrasound treatment, as taught by Makin et al. (pg. 1, paragraph [0004]).

9. Claims 14, 20 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich in view of Makin et al. as applied to claims 7, 10-11, 13, 16-17, 19, 22-23, 25, and 30 above, and further in view of Vitek et al.

As discussed above, Diederich in view of Makin et al. meet the limitations of claims 10, 16 and 22. However, they do not specifically disclose that the ultrasound emitting surfaces of the first, second and third ultrasound transducers together in their entirety have a substantially-spherically-focused shape. Vitek et al. disclose that their invention includes the use of a transducer with a substantially concave or bowl shape, preferably a "spherical cap" shape (column 3, line 65 through column 4, line 5). At the time of the invention, it would have

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been obvious to one of ordinary skill in the art to have the transducers have a substantially-spherically-focused shape. The motivation for doing so would have been to increase the targeted volume per sonication, as taught by Vitek et al. (column 1, lines 62-66).

10. Claims 18, 21, 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich in view of Makin et al. as applied to claim 7, 10-11, 13, 16-17, 19, 22-23, 25, and 30 above, and further in view of Unger et al.

The combined references of Diederich in view of Makin et al. do not specifically disclose that at all of the transducers have a plurality of ultrasound transducer elements, nor do they disclose that the transducers surface is substantially-entirely planar. Unger et al. disclose that their system includes an ultrasonic transducer assembly that comprises a linear array (16) of therapeutic transducer elements and also comprises of a first and second linear arrays of diagnostic transducer elements (12,14) (column 7, line 47 through column 8, line 13). As can be seen from Figure 1, each transducer array (i.e. therapeutic and diagnostic) has a plurality of ultrasound transducer elements (12,14,16). Further, the transducer elements are arranged on a common platform having a substantially planar upper surface (column 7, lines 19-31). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the ultrasound transducers in the invention of Diederich in view of Makin et al. have a plurality of ultrasound transducer elements. The motivation for doing so would have been to enlarge the field of view, increase the imaging sensitivity, and increase the resolution, as taught by Unger et al. (column 7, lines 24-31).

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11. Claims 28-29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich.

As discussed above, Diederich meets most of the limitations. Although they do not specifically disclose that their system has two ultrasound transducers, they do disclose that while 3 transducers are shown in Figures 1 and 2, the number and length of transducers can be varied (column 7, lines 14-22). At the time of the invention, it would have been obvious to one of ordinary skill in the art to Diederich's system have 2 transducers. The motivation for doing so would have been that two transducers might be more optimal for the spatial resolution and depth of penetration desired, as taught by Diederich (column 7, lines 14-22).


### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
ELENA MANTZ  
SPE 3768